REMARKS

Applicants wish to thank the Examiner for taking the time to conduct a telephonic interview with Applicants on January 23, 2004. Applicants acknowledge that the case has gone abandoned for failure to timely file a proper reply to the Office letter mailed on March 21, 2003.

Upon entry of this amendment, new claims 21-25 will remain pending and under consideration. Claims 1-20 have been cancelled. New claims 21-25 have been added.

Support for new claims 21-25 can be found throughout the specification, for example, at pages 3-8. Applicants submit that this Amendment is fully supported by the application as filed, and adds no new matter.

Rejection of Claims under 35 U.S.C. § 112, second paragraph

Claims 18-20 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to point out and distinctly claim the subject matter which the Applicant views as his invention.

Specifically, the Examiner asserts that the term "crystalline emulsion" is indefinite as it is "unclear how the claimed composition "can be both crystalline and emulsified simultaneously." Office Action, paper 7, at pg 2. Claim 18-21 have been cancelled and rewritten as claims 21-25 to clarify that the composition comprises an emulsion of covalently coated crystals emulsified in a carrier. Applicants submit that the aforementioned claim cancellations render the Examiner's rejection moot. New claims 21-25 do not recite "crystalline emulsion". Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner also alleges that the claims are indefinite for reciting "a catalyst" without naming a catalyst. Claim 18 has been cancelled in favor of new claim 21. New claim 21 does not recite "catalyst." Applicants submit that the claimed compositions do not in fact comprise a catalyst. As detailed in the specification at page 4, a catalyst, e.g. ammonia or steam, is used during the first step of the method for production of the coated crystal component of the claimed invention. However, the catalyst is removed during the heating step of coated crystal production. *Id.* Thus, the catalyst is not a component of the final composition, and the rejection of claim 18 is moot in view of the cancellation of claim 18 and absence of the term "catalyst" from new claim 21. Claim 20, which is directed to a method of producing the covalently coated crystals using a catalyst, has been cancelled and rewritten as new claim 23. New claim 23 specifies that the catalyst is selected from ammonia and steam. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

The Examiner also alleges that there is insufficient antecedent basis for the limitation "the coated crystals" in steps b and c of claim 20. Claim 20 has been cancelled and rewritten as new claim 23. The rejection of claim 20 is therefore moot. Applicants submit that the antecedents in new claim 23 are proper. Applicants therefore respectfully request reconsideration and withdrawal of claim.

Rejection of Claims 18-20 Under 35 U.S.C. 103

Claims 18-20 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Schmidt (U.S. Pat. No. 4,440,745) in view of Brieva et al. (U.S. Pat. No. 5,800,816). According to the Examiner, Schmidt et al. "discloses an abrasive emulsion where the abrasive crystals can be oxides of compounds such as Mg, Al, Ca and Si," which are useful as toothpaste or in an acne treatment. Office Action, paper 7, at pg. SAN /87026.1

6

3. The Examiner asserts that the reference suggests including silicone oils in the disclosed abrasives. *Id.* The reference allegedly "also teaches that the abrasives can be carried in an emulsion and are prepared by mixing and drying the resultant at a temperature of 230°F and further mixing the dried particles with an appropriate carrier." *Id.*

The Examiner maintains that what is lacking from Schmidt is a teaching of the particular silicone additive used in the composition. Office Action, paper 7, at pg. 3. The Examiner further asserts that "methicone is a well-known and used component of cosmetic compositions." *Id.* The Examiner also alleges that Brieva *et al.* "teaches a cosmetic composition where magnesium oxide particles are mixed with methicone" and it would have been obvious to one of ordinary skill in the art to follow the suggestions of Brieva *et al.* to arrive at the claimed invention. Office Action, paper 7, at pg. 4.

According to the Examiner, Schmidt provides the motivation to include silicon oils to coat and lubricate the particles, while Brieva *et al.* suggests the use of methicone as the silicon oil. *Id.*

Applicants respectfully disagree with the Examiner's characterization of the primary and secondary references. Furthermore, neither Schmidt nor Brieva *et al.*, alone or in combination, teaches all of the limitations of the presently claimed invention.

To establish the *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03, *citing In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Schmidt Does Not Teach The Covalently Coated Crystals As Claimed In The Present Invention.

Schmidt teaches porous silicic acid heteropolycondensates used as abrasives.

Schmidt at 1:55-6. The heteropolycondensates are prepared primarily from a siliconfunctional silane of general formula (I): SiX₄; and at least one organo-silane of the general formula (II): SiR'_aX(4-a); with X and as defined in the specification. *Id.* at 2:1
17. Optionally, the heteropolycondensates contain one of a group of involatile oxides.

Preferable oxides include oxides of Al, Ca, Mg, Ti, Zr, Zn, and Si. *Id.* at 2:35-42; 2:66-62. The abrasives taught by Schmidt contain only 0-40% of the oxide component. *Id.*2:53-54. Therefore, the abrasives taught by Schmidt cannot "be oxides ..." (emphasis added) as the Examiner suggests, but can contain oxides as a small component of a seminar suggests, where the oxide component does not exceed 40% by weight. Furthermore, none of the working examples provided by Schmidt contain oxides as a component of the heteropolycondensate abrasive. *Id.* at 4:26 to 5:18.

The compositions of Schmidt may also contain a variety of adjuvants including buffers, binders, polymers, thickeners, fillers, emulsifiers, extenders, emulsifiers, dyeing agents, silicone oils, lubricants, perfumes; deodorants; flavor-improving agents; conventional abrasives and/or natural or synthetic waxes. *Id.* at 3:54-67. Unspecified "silicone oils" are only one of a seemingly endless number of additional components suggested by Schmidt. Nowhere does Schmidt suggest that the silicone oil comprises a significant portion of the abrasive composition, nor does Schmidt provide a working example in which a silicone oil is a component of the composition.

In view of the foregoing, Applicants submit that Schmidt does not teach the crystals of the present invention. The claimed crystals of the present invention contain predominantly oxide, specifically magnesium oxide or a mixture of magnesium oxide and aluminum oxide. See specification at 3. The only non-oxide component of the claimed crystals is methicone, which comprises 1-2% by weight. See id. The claimed crystals of the present invention contain more than twice the amount of oxide as the claimed heteropolycondensates of Schmidt are permitted to contain (approximately 98-99% compared to 40% or less, respectively), while the working examples of Schmidt do not contain magnesium oxide or a mixture of magnesium and aluminum oxides. New claim 21, which replaces claim 18, has been rewritten to specify that the crystals of the present invention comprise magnesium oxide crystals or a mixture of magnesium oxide crystals and aluminum oxide crystals, which crystals are covalently coated with methicone. New '19 19 19 claim 21 also recites the weight percent limitation for methicone. Applicants respectfully submit that Schmidt does not teach the microdermabrasion crystals of the present invention as set forth in new claim 21. Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

Brieva et al. Does Not Teach The Claimed Covalently Coated Crystals Of The Present Invention Nor Does The Reference Suggest The Inclusion Of Methicone To Arrive At The Present Invention.

Brieva et al. does not teach the crystals of the present invention. Brieva teaches trimethylated silica particles having an average particle size of 0.5 millimicrons to 100 microns. Brieva et al. at 1:63-66. Preferred particles are spherical and may be combined with silicone fluids or other solvents (id. at 2:8-17) to give a cosmetic preparation that adheres well to the skin and displays reduced transfer resistance. See id. at 7:11-14. The

9

working examples in Brieva demonstrate that the "smooth and creamy" trimethylated silicas remain on skin for up to 10 to 12 hours. *Id.* at Example 7.

In contrast, the present invention is a dermatological product with abrasive properties that is applied to the skin for microdermabrasion and then removed. Specification at 7-8. The properties of the invention disclosed in Brieva et al. are significantly different than those of the present invention. The covalently coated crystals of the present invention are much larger than the trimethylated silica particles of Brieva et al.: the crystals of the present invention preferably have a diameter of 100-1200 microns (Specification at 3) compared to the 0.5 millimicrons to 100 microns particles in Brieva et al. (Brieva et al. 1:65-66). Independent claim 18 has been cancelled and rewritten as new claim 21 to recite the crystal size limitation of 100-1200 microns.

The crystals of the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and do not independently stick and the present invention are abrasive and abrasive are abrasive and abrasive are abrasive and abrasive are abrasive abrasive and abrasive are abrasive are abrasive are abrasive are abrasive abrasive are abrasive are abrasive are abrasive are to the skin, which contrasts significantly with the cosmetic preparations of Brieva et al. which are formulated for improved skin adherence and reduced transfer resistance. The ordinarily skilled artisan would understand that a dermabrasive formulation would be applied to the skin for a short time and then removed. It would be undesirable to retain the dermabrasive formulation of the present invention on the skin for an extended period of time or to provide a dermabrasive composition that was difficult to remove. The claimed crystals of the present invention are emulsified in a carrier so that the overall formulation has a gel-like quality sufficient to keep the emulsion on human skin during a short manual dermabrasion skin rejuvenation treatment. Specification at 3. The crystals in the emulsion are moved around on the skin to provide the dermabrasive effect, and the removed after use in dermabrasion. Specification at 5-6. Claim 18 has been cancelled and rewritten as new claim 21, reciting the limitation that the emulsion comprises a gel-SAN /87026.1

10

like quality sufficient to keep the emulsion on the skin during skin rejuvenation treatment.

In contrast, the compositions taught by Brieva et al., are designed to be retained on the skin for up to 12 hours and resist transfer off the skin. Brieva et al. 1:38-39; Example 7. Thus the trimethylated silica particles of Brieva et al., are distinct from those of present invention.

The magnesium oxide particles that the Examiner cited in Brieva *et al.* are one of a number of types of dry particulate matter that may be used as <u>vehicles</u> for the trimethylated silica particles. *Id.* at 4:52 to 5:18. Brieva teaches that the trimethylated silica particle compounds may be water/oil emulsions (*e.g.*, creams or lotions, *id.* at 4:18-35), or incorporated into a vehicle such as a powder, blush or eyeshadow (*id.* at 52-56).

Optionally, the powder particles can be treated with agents including silicone oil to the render them hydrophobic. *Id.* 5:8-13

The powders of Brieva et al. differ substantially from the compositions of the present invention at least in the following ways. First, the powders described in Brieva et al. are cosmetic face powders. Id. at 4:56-58. The ordinarily skilled artisan would understand that such powders are not abrasive. The non-abrasive face powders of Brieva et al. are distinctly different than the crystals of the present invention which are formulated to have abrasive qualities. Specification at page 3. Claim 18 has been cancelled in favor of new claim 21. New claim 21 has been re-written to recite the limitation that the covalently coated crystals of the present invention have sharp edges.

Second, the particle size of the magnesium oxide powders disclosed in Brieva is in the range of .02 to 200 microns. Brieva et al. at 4: 56-58. In contrast, the crystals of

the present invention are generally larger. *See* specification at 3. As indicated above, new claim 21 has been re-written to recite the size limitation for the covalently coated crystals of the present invention.

Furthermore, in Brieva *et al.* methicone or a similar nonvolatile nonfluorinated silicone is not specified as a covalent coating for magnesium or aluminum oxide particles, but instead is mixed with the trimethylated silica particles to effect a composition that <u>adheres</u> to the skin and <u>resists transfer</u>. Brieva *et al.* 1:59-60; 3:50-62.

In summary, Brieva et al. does not disclose the claimed covalently coated crystals of the present invention, nor does it disclose a formulation of abrasive, covalently coated crystals in a carrier. Indeed, Brieva et al. discloses a cosmetic composition that is formulated to remain on the skin for an extended period of time, rather than be washed off or otherwise removed shortly after application. Thus, rather than suggest that methicone could be a suitable component of an abrasive dermabrasion preparation, Brieva et al. actually teaches away from such an abrasive formulation or composition by demonstrating the skin-retentive properties of compositions containing methicone or other silicone oils.

Applicants submit that neither Schmidt not Brieva et al., alone or in combination, teaches all the claim limitations of the present invention as presently claim and actually teaches away from an emulsion of covalently coated crystals in a carrier useful for dermabrasion. Applicants therefore respectfully request reconsideration and withdrawal of the obviousness rejection under U.S.C. 103(a).

Applicants petition under 37 C.F.R.§1.136(a) for a three month extension of time and hereby authorize the Commissioner to charge the fee required under 37 C.F.R. §1.17(a) to our Deposit Account No. 50-2613.

In view of the foregoing, Applicants believe that the entire application is in condition for allowance and such action is respectfully requested. If it is believed that prosecution can be assisted thereby, the Examiner is invited to contact Applicants' undersigned Representative at the below-listed telephone number.

Respectfully submitted,

PAUL HASTINGS JANOFSKY &WALKER LLP

Reg. No. 47,224

Dated:

JKB/jc

Paul, Hastings, Janofsky & Walker LLP

P.O. Box 919092

San Diego, CA 92191-9092 Telephone: (858) 720-2500

Facsimile: (858) 720-2555